

PSJ3

Exhibit 441

## ONDCP

### AMA TALKING POINTS

#### ADDRESSING PUBLIC HEALTH CRISIS

- We appreciate the leadership of this Administration in bringing national and local attention to the prescription drug health crisis.
- Our physicians are on the frontlines and continue to report on the devastating impact on families and the acute and immediate need for policies and strategies to prevent addiction and to treat those who suffer.
- ONDCP's emphasis on a public health approach is welcomed strongly in the House of Medicine and reaffirmed again during our Annual Meeting last year.

#### EDUCATION

- When we first met with ONDCP staff we committed to increasing our efforts to improve and expand physician education.
- Based on grant support from the Substance Abuse and Mental Health Services Administration and as part of the Prescriber Clinical Support System for Opioid Therapies, the AMA offers an updated comprehensive course on pain management that reflects contemporary concerns about the role of opioid analgesics in the management of chronic pain. Course materials are freely available.
- In the most recent module, the FDA participated to provide a review of the modifications to the labeling of extended release and long acting opioids.
- As part of our collaborative efforts in the PCSS-O, the AMA also is offering a series of free webinars on various aspects related to the intersection of pain, substance use disorders, and responsible opioid prescribing.
- We are actively promoting positive incentives as well as educational opportunities. We have worked to promote the FDA's REMS program that just came on line last year.

#### ENGAGE WITH OTHER STAKEHOLDERS

- We took a leaf out of your book and have worked closely with other stakeholders to address this crisis at the regional and national levels.
- We have continued to engage medical specialty societies and state medical associations on this topic. In addition to hosting ONDCP at several AMA meetings in the past couple years, the issue of combatting diversion has been a key part of AMA physician leadership briefings and educational forums for state medical associations—most recently last week.
- We are working with this Alliance as well as with a group convened by the National Association of Board of Pharmacy which involves the DEA as an observer along with the Federation of State Medical Boards.
- We have continued to work with NCOIL, FSMB, the NGA and others such as the Harm Reduction Coalition.
- We also are working to obtain better state based data to help guide policies that meet the varied and diverse challenges of this crisis.

#### NASPER

- We are still trying to obtain adequate funding for prescription drug monitoring programs.
- These essential tools must be funded, maintained and modernized to ensure their long-term ability to help combat prescription drug abuse, misuse and diversion.
- The Congressional Research Service estimates that PDMP costs may vary widely, with start-up costs ranging from \$450,000 to over \$1.5 million and annual operating costs ranging from \$125,000 to nearly \$1 million.
- There is a pressing need right now for Congress to appropriate funding for NASPER, but state and private funding will be needed to maintain and undertake much needed upgrades and modernization of PDMPs.
- The AMA continues to strongly advocate for federal and state funding to ensure PDMPs have the support they need.
- We also are strongly supporting efforts by the National Association of Boards of Pharmacy (NABP) to promote the “PMP InterConnect” program, an interstate data sharing hub that is operated by NABP at no cost to the states.
- NABP reports that by the first quarter of 2014, 25 states will be using the system and sharing data across state lines.
- Despite this success and positive impact on the public health, PDMPs are still being asked to comply with the Bureau of Justice Assistance (BJA) technological standards that reportedly are onerous and do not enhance the program.
- We understand that congressional leaders have urged BJA to approach this issue with greater flexibility, but it has not been forthcoming.
- NASPER grants do not include such requirements which should accelerate the uptake of the InterConnect program and enhance the quality of the data physicians and other prescribers and dispensers receive. Furthermore, the public health focus of NASPER is essential since over 95 percent of PDMP usage comes from healthcare providers.

#### TREATMENT

- This overdose trend is exacerbated by the limited access to existing options to treat prescription drug addiction, limited patient resources or insurance coverage for such treatment, and equally low awareness of where to go for help among many who suffer from addiction.
- The availability of in-patient programs to treat prescription drug addiction is far exceeded by the number of individuals requiring such treatment.
- Unfortunately, despite efforts to increase the number of physicians who offer out-patient treatment, the number participating in such programs remains far too low to meet the existing and growing need of individuals requiring such medical care.
- Low awareness among physicians may be one factor for the current participation rates, but other factors that have been raised include the regulatory requirements and interactions with the DEA—which conducts onsite unannounced audits without regard to the operations of a medical practice which can be highly disruptive to scheduled patients—including those in practices where the majority of the patients are not receiving medical care for addiction.
- We would like to work with SAMSHA, DEA, and CDC to develop assessments of state-based and local capacity for treatment so that we can work with state medical associations to identify opportunities to increase treatment.

- Physicians are reporting that they are not receiving the support they need from the medical or public health infrastructure.
- Community-based programs for addicts and at-risk youth are lacking, and mental health networks and pain specialists are nonexistent in many areas. We have reports from emergency department physicians that they have patients waiting for detox or treatment beds, but none are available.
- In addition legislative efforts designed to reduce supply or create practice standards can make treating pain patients more difficult for physicians.

#### DISPOSAL

- We know that diversion can start in the medicine cabinet.
- The process of rules and regulations governing disposal of unused prescription drugs remains too complicated.
- We urge you to broker an effort among a diverse array of federal agencies such as the EPA, DEA, OSHA, and the DOT along with, for example, NGA to simplify and/or streamline the drop-off, storage, transportation, and destruction of unused prescription drugs. Disposal of controlled substances, in particular, appears to be prohibitively expensive and highly regulated.
- Efforts to clarify and simplify this process would be quite welcome.